



Food and Drug Administration
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March 20, 2015

Blue Belt Technologies, Incorporated
Mr. Richard G. Confer
Vice President of Regulatory Affairs
2828 Liberty Avenue, Suite 100
Pittsburgh, Pennsylvania 15222

Re: K143668
Trade/Device Name: Navio™
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: Class II
Product Code: OLO, HSX, HRY, KRR, NPJ
Dated: December 22, 2014
Received: December 24, 2014

Dear Mr. Confer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA).

You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K143668

Device Name

Navio

Indications for Use (Describe)

The Navio system is intended to assist the surgeon in providing software-defined spatial boundaries for orientation and reference information to anatomical structures during orthopedic procedures.

The Navio system is indicated for use in surgical knee procedures, in which the use of stereotactic surgery may be appropriate, and where reference to rigid anatomical bony structures can be determined. These procedures include unicondylar knee replacement and patellofemoral arthroplasty.

The Navio system is indicated for use with cemented implants only.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

Navio™ Traditional 510(k) Premarket Notification

Section 6: 510(k) Summary

510(k) Summary

510(k) Owner	Blue Belt Technologies 2905 Northwest Blvd Ste. 40 Plymouth, MN 55441 UNITED STATES Tel: (763) 452-4905 Fax: (763) 452-4675
Contact Person	Richard G. Confer Vice President of Regulatory Affairs and Quality Assurance Tel: (412) 683-3844 x 4106 Email: rconfer@bluebelttech.com
Date of Submission	December 22, 2014
Classification Reference	21 CFR 882.4560
Product Code	OLO
Supported Codes	HSX, HRY, KRR, NPJ
Common/Usual Name	Orthopedic Sterotaxic Instrument
Trade/Proprietary Name	Navio™
Predicate Device(s)	Blue Belt Technologies Navio System (K140596)
Reason for Submission	Expanded Indications to add NPJ as a supported product code

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Intended Use

The Navio system is intended to assist the surgeon in providing software-defined spatial boundaries for orientation and reference information to anatomical structures during orthopedic procedures.

The Navio system is indicated for use in surgical knee procedures, in which the use of stereotactic surgery may be appropriate, and where reference to rigid anatomical bony structures can be determined. These procedures include unicondylar knee replacement and patellofemoral arthroplasty.

The Navio system is indicated for use with cemented implants only.

This intended use statement is the same as the predicate, Navio System per K140596, and adds product code NPJ per regulation 888.3560 as a supported product code.

Device Description

The Navio system is a computer-assisted orthopedic surgical navigation and surgical burring system. The system uses established technologies of navigation via a passive infrared tracking camera to aid the surgeon in establishing a bone surface model for the target surgery and to plan the surgical implant location based on predefined bone landmarks and known configuration of the surgical implant. The Navio system then aids the surgeon in executing the surgical plan by using a standard off-the-shelf surgical drill motor and bur (eMax 2 Plus System - K080802), which has been adapted using a tracking system. The surgical bur is located in a handpiece, which allows the bur to move within the handpiece. In the Navio system the software controls the position of the tip of the surgical bur relative to the end of a guard attached to the handpiece and prohibits the bur from cutting bone as it approaches the planned target surface. As the planned surface is reached, the tip of the bur is fully retracted within the guard.

An alternate mode of operation is the speed control mode. In this mode the speed of the bur is controlled and the bur stops as the planned surface is reached. In this mode of operation the bur does not retract into the guard. This mode of operation is useful in shaping surfaces of the condyle as well as placing post holes.

The Navio computer system maintains a log of the patient data and procedure data. Each entry is date and time stamped. Data log entries include date and time stamp for data line entry, patient and procedure ID, implant ID, step in process, and error messages. This data can be archived to a CD upon demand at the end of the procedure.

The following diagram shows the primary workflow steps in each application, UKR and PFA. Though the two procedures are very similar, they are mutually independent and cannot be planned or completed in parallel.

Note: *The workflow has not changed from the predicate, Navio per K140596.*

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Figure 6-1

Navio™ Traditional 510(k) Premarket Notification - Section 6

Table 6-1: Summary of Technological Similarities with Predicates

Devices	Blue Belt Technologies Navio	Predicate A Blue Belt Technologies Navio (K14059)
<u>Indications for use</u>	The same as Predicate	<p>The Navio system is intended to assist the surgeon in providing software-defined spatial boundaries for orientation and reference information to anatomical structures during orthopedic procedures.</p> <p>The Navio System is indicated for use in surgical knee procedures in which the use of stereotactic surgery may be appropriate, and where reference to rigid anatomical bony structures can be determined.</p> <p>These procedures include unicondylar knee replacement and patellofemoral arthroplasty.</p> <p>The Navio system is indicated for use with cemented implants only.</p>
<u>Supported Product Code</u>	Supported Product Codes: HSX, HRY, KRR, NPJ	Supported Product Codes: HSX, HRY, KRR
<u>Environment of Use</u>	Same as Predicate	Used by trained orthopedic surgeons in an Orthopedic surgical suite.
<u>Technological Characteristics</u>	Same as Predicate	<p>The Navio system uses established technologies to prepare bone for attachment of implant components. Navio uses intraoperative data collection (image- free or non-CT data generation) to create a model of the patient's femur and/or tibia, dependent on the procedure being performed, and allows the surgeon to prepare a surgical plan.</p> <p>The Navio system uses predefined boundaries generated during the planning process to control the motion of the surgical bur and limit the amount of bone removed in order to shape the condyles, tibial plateau, or</p>

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Devices	Blue Belt Technologies Navio	Predicate A Blue Belt Technologies Navio (K14059)
		<p>patellofemoral joint in preparation for placement of the surgical implant.</p> <p>Bur cutting is controlled either by retracting the bur in a guard, or by controlling the speed of the bur as the target surface is approached.</p>
<u>Construction</u>	Same as Predicate	Consists of an IR image system (Northern Digital Polaris), reflective trackers, computer, user interface display, various probes, a surgical bur, bur guards, bone screws, and clamps.
<u>Pre-Surgical Planning Method</u>	Same as Predicate	Uses data collected intra-operatively by surgeon during the initial surgical procedure to generate a real-time plan of cut surfaces.
<u>Imaging Requirements</u>	Same as Predicate	None preoperative. Possible post-operative to verify implant placement after surgeon finalizes placement.
<u>Tool manipulation</u>	Same as Predicate	<p>Controlled by retracting surgical bur into a guard as a function of proximity of bur to planned cut surface. Also, speed of bur changes as a function of proximity to planned cut surface.</p> <p>The surgeon has control of the tool at all times. Position of the bur is based on navigated guidance and planning of desired cut surface.</p>
<u>Feedback that boundary has been reached</u>	Same as Predicate	<p>Visual (color-coded surface on GUI) and audio indicators as feedback that the boundary has been reached.</p> <p>Withdrawal of bur or reduced bur speed.</p>
<u>Visual indicator</u>	Same as Predicate	<p>Color changes as surgical bur approaches planned cut boundary.</p> <p>Magenta (purple) is the starting bone surface (>3 mm from target surface). Intermediate colors (blue and green) indicate bone to be removed. Blue indicates 2 mm to target surface. Green indicates 1 mm to target surface. Colors are correlated to the distance</p>

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Devices	Blue Belt Technologies Navio	Predicate A Blue Belt Technologies Navio (K14059)
		from planned cut surface in 1mm increments. Red indicates over cut exceeding 0.5 mm.
<u>User Override</u>	Same as Predicate	Surgeon has full control of handpiece at all times. Cutting bur operation speed is enabled by surgeon operated footswitch. The computer program only modifies the speed up to the limit set by the surgeon pressing the footswitch. The surgeon always has the ability to move the handpiece away from the cut surface or disable the footswitch.
<u>Accuracy of placement of implant</u>	Same placement accuracies as Predicate for patellofemoral knee replacements (algorithms have not changed). Onlay Patellofemoral component RMS placement error along any single axis averaged 0.884 mm and 1.013°. Inlay Patellofemoral component RMS placement error along any single axis averaged 0.462 mm and 1.028°.	Onlay Patellofemoral component RMS placement error along any single axis averaged 0.884 mm and 1.013°.

Nonclinical Testing

Design verification tests were performed on the Blue Belt Technologies Navio system to support inlay patellofemoral implant placement as a result of the risk analysis and product requirements. Testing included software data base reviews, bench verification testing, user manual/labeling inspection, drawing inspections, and a clinical simulation (usability testing). Simulated-use testing included testing in simulated knees (sawbones) and cadaver lab testing. Users included surgeons, physician's assistants, and technical support personnel who were able to successfully use the Navio system and place inlay patellofemoral implants per Blue Belt Technologies' specifications and implant manufacturer's specifications after being adequately trained.

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Discussion of Similarities and Differences

The Navio system uses established technologies to prepare bone for attachment of implant components. Navio uses intraoperative data collection (image-free or non-CT data generation) to create a model of the patient's femur and tibia and allow the surgeon to prepare a surgical plan. The Navio uses predefined boundaries generated during the planning process to control the motion of the surgical bur and limit the amount of bone removed in order to shape the condyles, tibial plateau, or patellofemoral joint in preparation for placement of the surgical implant. This is equivalent to the methodology used by the NavioPFS™ system except for the Navio's additional capability to prepare the patellofemoral joint for implant.

The Navio uses predefined boundaries generated during the planning process to control the motion of the surgical bur and limit the amount of bone removed in order to shape the condyles, tibial plateau, and/or the patellofemoral joint in preparation for placement of the surgical implant.

This submittal supports the expanded indication for use of the Navio system to place inlay patellofemoral implants using the same techniques used in the predicate Navio system.

Though the UKR and PFA procedures are very similar, they are mutually independent and cannot be planned or completed in parallel. If the user is completing a bi-compartmental knee joint replacement in which a patellofemoral arthroplasty and a unicondylar knee replacement are both being performed, preparation of the patellofemoral joint must be completed independently of the preparations of the femoral condyle and tibial plateau surfaces.

Clinical Testing

No human clinical tests were conducted to determine safety and effectiveness of the Navio system.

Summary and Conclusions

The Navio system described in this submittal has the same intended use and the same technological characteristics as the Navio system (K140596). Non-clinical testing was completed to verify that the use of the Navio system to assist with the placement of inlay patellofemoral implants does not raise any new issues of safety or effectiveness. The information presented in this 510(k) notification demonstrates that the Navio, when used to place an inlay patellofemoral implant, is as safe and effective as Navio™ (K140596).